

**A Pilot Study to Estimate the Impact of a Screening and Referral Service on
Contraceptive Use**

Research Design and Analysis Plan

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Changelog:

July 18, 2017: Added table of contents; added Section 6 on ClinicalTrials.gov registration

July 24, 2017: Added ClinicalTrials.gov ID number

1. Specific aims

Based on global projections, meeting the unmet demand for contraceptives would prevent more than two-thirds of unintended pregnancies and more than two-thirds of maternal deaths. Voluntary family planning has also been shown to improve newborn health outcomes, advance women's empowerment, and bring socioeconomic benefits through reductions in fertility and population growth. Yet among the populations that would benefit the most from family planning, uptake remains too low.

The specific aim of this pilot study is to estimate the impact of a new digital health service on the uptake of family planning among Kenyan women with an unmet need for contraception. This service promotes uptake by offering free screening and referral. Women text the service for free, complete a short automated screening over the phone, and receive a list of recommended methods and a referral to local family planning providers offering those methods. The main hypothesis is that the service will increase the uptake of family planning among these users.

2. Intervention: A digital family planning screening and referral service

Women text the service and receive a free call back to complete an automated family planning counseling session that results in a set of recommended methods that fit the client's preferences and goals. The client is matched to several local family planning providers that offer these methods, and the service sends a referral code via SMS that the client can redeem at the facility. Unless the client requests otherwise, the service follows-up on every automated counseling session. When someone receives a referral code, the service tracks them through their encounter with a local provider (public and private) to learn about their experience with the service, the provider, and their choice in contraception (or not). The service also follows-up with clients who do not act on referrals to better understand their reasons tries different behavioral nudges that encourage the caller to visit a facility (e.g., sending a transportation voucher). The service does not pay for any costs the client may incur at the facility.

3. Research Design

The service is available to anyone living in the catchment area, so it is not possible to randomly assign access to the service and estimate impact through a traditional randomized controlled trial (RCT). Likewise, at this early stage it is not be feasible to randomize access at a higher level, such as counties or subcounties. In situations like this, a variation on the traditional randomized controlled trial called a randomized encouragement design can be very effective.

In a randomized encouragement design (RED), participants are randomized to receive an invitation or special encouragement to receive a treatment. Not everyone who is encouraged will take up the service, but as long as those randomly selected to receive the encouragement (the treatment group) use the service at a higher rate than the control group, the impact of the service can be estimated.

3.1 Setting and Participants

The target population for this study is women who have an unmet need for family planning; that is, women who are not currently using family planning but wish to delay or prevent pregnancy. Participants will be recruited from markets throughout Bungoma County in areas where the service is active at the time of recruitment.

3.1.1 Inclusion and Exclusion Criteria

To be eligible for the study, women must:

1. be between the ages of 18 and 35 (inclusive);
2. have an [unmet need](#) for family planning;
3. live in the service catchment area;
4. demonstrate phone ownership;
5. opt-in to receiving calls and/or SMS messages from the study team;
6. demonstrate basic ability to operate study tablet; and
7. consent to participate in the study.

Phone ownership is a requirement because the design will lead to two-sided non-compliance, and it will be necessary to track participants use (or not) of the service. Women need to own their own phones to decrease the likelihood of calling or texting the service from a number not registered with the study. Women do not need special phones or data plans to participate, just a phone that can make and receive calls and text messages.

Women who are pregnant or < 4 months postpartum are ineligible because they will not be ready to act on family planning referrals.

3.1.2 Recruitment

We will rent stall space in several Bungoma markets on market days with signage advertising our study on women's health. Women between the ages of 18 and 35 (inclusive) and in possession of a phone will be invited to complete a brief screening on a tablet computer. Interested women will use headphones to listen to recorded questions and tap the screen to record their answers (audio computer-assisted self interviewing, ACASI, with female enumerators standing by to assist when needed).

If a woman is eligible to participate in the study based on her responses to the screening, the tablet will instruct the enumerator to review the informed consent form with her. If the woman consents to participate, the enumerator will record her name and contact details in a study register. Her study register entry will be associated with a unique ID that the enumerator will enter into the tablet before closing out the screening.

We will not collect identifying information from any woman who is not eligible or declines to participate in the study.

Every woman who completes the brief screening will receive an honorarium of Ksh 200 to appreciate their time answering study questions. This honorarium will be provided regardless of whether a woman: (i) is eligible to participate in the study or (ii) consents to participate in the study.

If we do not generate sufficient interest in the study via the methods described above, we will create a print advertisement with a phone number to call and complete the screening over the phone through an automated interactive voice response system. Female enumerators will then call back eligible women and invite them to visit the market stand to complete the screening and enrollment process.

3.2 Procedures

After a woman enrolls in the study, she will be randomized to 1 of 2 study arms: (i) encouragement to try the service or (ii) control (no encouragement). See the study workflow in Figure 1.

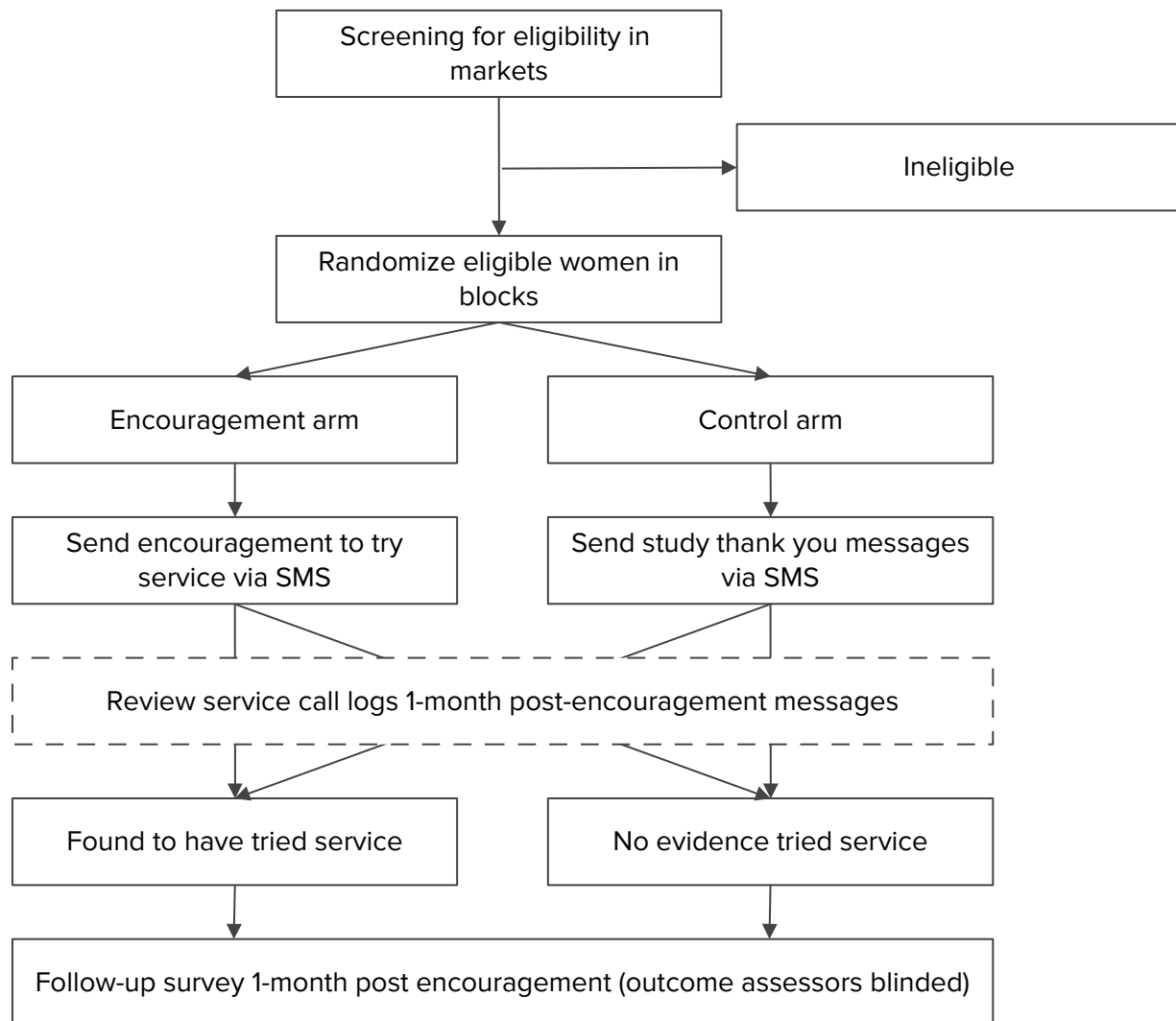


Figure 1. Study workflow.

Women randomized to the encouragement arm will receive an invitation via SMS to call the service and complete the free family planning screening (plus ~\$2.00 USD phone credit). Women randomized to the control arm will receive a different set of messages that do NOT include any special encouragement to try the service.

This study will likely result in two-sided non-compliance with respect to random assignment:

1. Every woman randomized to the encouragement arm will receive a special invitation to try the service, but only a subset of women in this group will take up this offer.
2. Women randomized to the control arm will NOT receive a special invitation to try the service, but some will learn about the service through other channels and try it out on their own.

Encouragement designs account for this non-compliance by estimating the local average treatment effect (LATE). In this study, LATE will be the effect of trying the service on 'compliers'—those who tried the service because they were randomly encouraged to but would not have called otherwise.

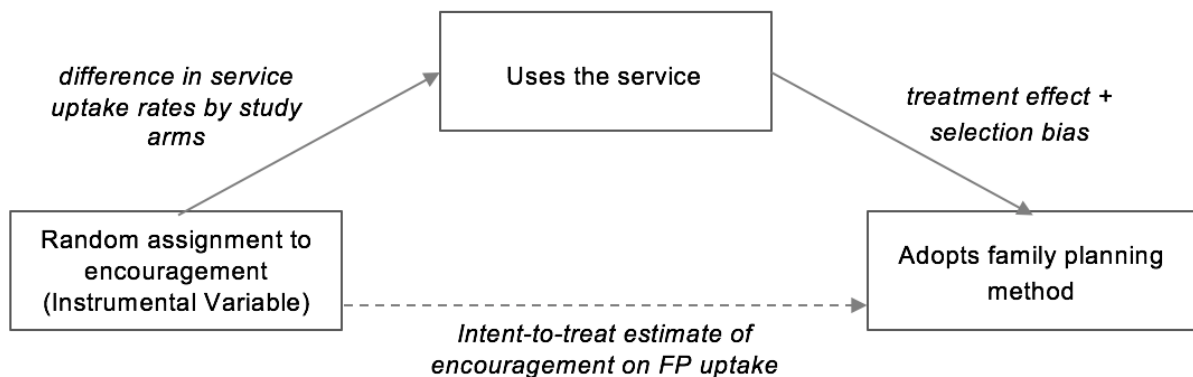


Figure 2. Randomized encouragement as an instrumental variable.

In order to estimate LATE, we will collect data on two key indicators: (i) use of the service and (ii) family planning uptake.

(i) Use of the Service. We will use two data sources to determine whether an enrolled participant tried the service.

First, we will examine the service call logs to see if the phone numbers linked to study participants appear.

- Tried the service: Study participant phone number is present in service call logs
- Completed screening: Referral code sent to study participant phone number via SMS (indicator of completed screening)

Second, we will conduct a follow-up survey with all study participants 1-month after enrollment messages are sent (per block). This data collection will uncover potential use cases in which a woman called the service from a phone number not known to the study team.

(ii) Family planning uptake. During the follow-up survey we will ask ALL women if they started using any modern method contraception since the start of the study.

3.3 Analysis Plan

3.3.1 Sample Size

In a traditional parallel randomized controlled trial, we would need a total sample size of 48 women to detect a shift of 30 percentage points from 5% uptake of family planning in the control group to 35% uptake in the treatment group, assuming alpha of 5% and power of 80%. However, power calculations for randomized encouragement designs are complicated by the fact that only a portion of the treatment group will take up the treatment. Since we expect that the encouragement will increase the probability of using the service from 20% (control) to 80% (treatment), we must increase the sample by a factor of 2.8 [$1/(0.8-0.2)^2 = 2.8$] to 134.

3.3.2 Primary Outcome

The primary outcome will be whether or not a woman reports adopting a modern method of family planning.

3.3.3 Estimate Impact

Randomizing encouragement will only impact the probability of using the service, not the probability of family planning uptake. To estimate the impact of the service on family planning uptake, we will use random assignment to encouragement as an instrumental variable. Regressing uptake of family planning on the assignment to encouragement will give us the intent-to-treat estimate. We will estimate LATE by dividing the intent-to-treat estimate by the differential uptake of the service by treatment assignment. We will use IV regression to obtain robust standard errors.

3.3.4 Subgroup Analyses

We hypothesize that the intervention effect will be larger for women with more education and for women who have used contraception in the past (discontinued). We will also examine subgroup effects by marital status (married/in-union vs not married/in-union).

4. Study Team

Principal Investigator: Eric Green, Ph.D. (eric.green@duke.edu)

Co-Investigator: Violet Naanyu, Ph.D.

Student Researcher: Arun Augustine

5. Conflicts of Interest

Dr. Green is a co-founder of the digital health service. He has equity in the company that operates this service, and he has a seat on its Board of Directors. Duke University has a Conflict of Interest Management Plan on file to guide his involvement in research involving this service.

6. ClinicalTrials.gov Registration

July 12, 2017: Record created

July 18, 2017: Record release for PRS Review

July 24, 2017: Public record posted ([NCT03224390](#))